

REMARKS

Claims 1-12, 18-23, 25-32, 34-36 and 38-48 are pending. Claims 13, 14, 24, 33 and 37 are canceled and claims 1-10, 18, 25-32, 34 and 35 are amended herein. The attached Appendix includes marked-up copies of each rewritten paragraph (37 C.F.R. §1.121(b)(1)(iii)) and claim (37 C.F.R. §1.121(c)(1)(ii)).

Claims 13, 14 and 37 were withdrawn from consideration. Claims 13, 14 and 37 are canceled herein.

The specification is objected to for failing to include an Abstract. An Abstract is added herein. Therefore, the objection should be withdrawn.

Claims 1-12, 18-36 and 38 are objected to for lacking an article. Claims 7-12, 18-23, 33-36 and 38 have an article. Claims 1-6 and 25-32 have been amended to include articles. Therefore, this objection should be reconsidered and withdrawn.

In addition, claims 33-35 are objected to based on the recitation of elements a), b), c), recited in the body of these claims without being enclosed in parentheses. Claims 33 has been canceled. Claims 34 and 35, as well as other claims that include these designations, have been amended to include complete parentheses. Therefore, this objection should also be withdrawn.

Claims 1-12, 15-36 and 38 are rejected under 35 U.S.C. §112, second paragraph. In view of the above amendments, Applicants respectfully traverse the rejection.

Claims 1-4 are rejected based on the recitation of "nucleic material of the retroviral genomic type." The expression "of retroviral type" is defined in this present specification at page 4, lines 8-13, as being "the characteristic according to which the nucleic material considered comprises one or more nucleotide sequences related to the organization of a retrovirus, and/or to its functional or coding sequences."

Claims 1 and 7 are indicated to be vague and indefinite based on the term "equivalent." Claim 1 has been amended to remove the term "equivalent." Claim 7 has been amended to define equivalent sequences as those having at least 50% homology to the specifically recited sequences.

Claim 1 is also objected to based on the term "reference nucleotide sequence." The term "reference nucleotide sequence" is merely used to provide antecedent basis for later recitations of this nucleotide sequence. That is, use of the term "reference" provides no separate meaning other than to allow the reference nucleotide sequence to be referred to in dependent claims.

Claim 2 is objected to based on the phrases "capable of" and "functional part." Claim 2 has been amended to delete the phrase "capable of." The term "functional" as it relates to nucleotide sequences is defined in the present specification at page 10, lines 5-8, to mean "the characteristic according to which a nucleotide sequence, a nucleic material or a nucleotide fragment comprises an 'informational sequence.' " The term "informational sequence" is defined at page 10, lines 11-16, as:

any ordered sequence of monomers whose chemical nature and the order in a reference direction, constitute or otherwise a functional information of the same quality as that of the natural nucleic acids, for example a reading frame encoding a protein, a regulatory sequence, a splicing site or a recombination site.

Based on this definition, it is respectfully submitted that the term "functional part" would be understood by one of ordinary skill in the art.

Claims 3, 12 and 27 are rejected based on the recitation of the term "fragment." It is respectfully submitted that this term would be understood by those of ordinary skill in the art. In particular, it is not limited to a particular length, although it would not read on a single nucleotide since one of ordinary skill in the art would not refer to a single nucleotide as a nucleic acid fragment. (It is noted that the term "nucleic acid" does not refer to a single

nucleotide but to a macromolecule formed by polymerization of nucleotides.) The source of the fragment is undefined in this claim, although it is further defined in claims 28 and 29.

Claim 7 is rejected based on the phrase "partial and complete." Claim 7 has been amended to delete this recitation.

Claims 8 and 10 are rejected based on the phrase "capable of hybridizing specifically." Claims 8 and 9 have been amended to delete this language.

Claim 9 is rejected based on the recitation of a "marker." As suggested in the Office Action, this claim has been amended to replace the term "marker" with "label."

Claim 12 is rejected for lacking clear and positive prior antecedent basis for the term "nucleotide fragment" in claim 7. However, the preamble of claim 7 clearly recites "a nucleotide fragment." Thus, there is clear antecedent basis for this phrase in claim 12.

Claim 18 is rejected based on use of the term "and/or." Claim 18 has been amended to remove this terminology.

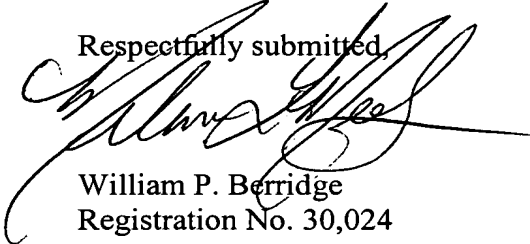
Claim 20 is rejected for being drawn to a non-elected embodiment. It is respectfully submitted that once the nucleic material of claim 1 is determined to be allowable, the composition of claim 20 should be allowable whether it is designated a diagnostic or therapeutic composition without any additional search or consideration. Thus, the Examiner is respectfully requested to reconsider the restriction among the subject matter of claim 20 and allow claim 20 without amendment to delete the therapeutic composition. In any event, including the non-elected subject matter in claim 20 clearly does not render it indefinite.

The claims clearly recite the invention. Therefore, the rejection under 35 U.S.C. §112, second paragraph, should be reconsidered and withdrawn.

In view of the above amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Favorable consideration and prompt allowance are therefore respectfully requested.

Should the Examiner believe anything further would be desirable in order to place the application in condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,



William P. Berridge
Registration No. 30,024

Melanie L. Mealy
Registration No. 40,085

WPB:MLM/jam

Attachments:

Abstract
Appendix

Date: October 30, 2002

OLIFF & BERRIDGE, PLC
P.O. Box 19928
Alexandria, Virginia 22320
Telephone: (703) 836-6400

<p>DEPOSIT ACCOUNT USE AUTHORIZATION Please grant any extension necessary for entry; Charge any fee due to our Deposit Account No. 15-0461</p>

APPENDIX

Changes to Abstract:

An Abstract has been added to the specification.

Changes to Specification:

Page 1, lines 4-10:

The present invention relates to a new nucleic material of the endogenous retroviral genomic type, various nucleotide fragments comprising it or which are obtained from said material, as well as their use as a marker for at least one autoimmune disease or a pathology which is associated with it, a pathological pregnancy or an unsuccessful pregnancy.

Page 10, lines 5-8:

- "functional" is understood to mean the characteristic according to which a nucleotide sequence, a nucleic material or a nucleotide fragment comprises an "~~an~~ informational sequence₁";

Changes to Claims:

Claims 13, 14, 24, 33 and 37 are canceled.

Claims 39-48 are added.

The following is a marked-up version of the amended claims:

1. (Twice Amended) ~~Nucleic~~A nucleic material of the retroviral genomic type, in an isolated or purified state, ~~whose genome comprises~~ comprising a reference nucleotide sequence selected from the group consisting of sequences of SEQ ID NOs: 1 to 15, their complementary sequences, and ~~their equivalent sequences~~ that exhibit for every sequence of 100 contiguous monomers at least 70% homology with said sequences of SEQ ID NOs: 1 to 15, respectively.

2. (Twice Amended) ~~Nucleic~~A nucleic material of the retroviral genomic type, in an isolated or purified state, ~~whose genome comprises~~ comprising a reference nucleotide

sequence, encoding any polypeptide exhibiting, for ~~any every~~ contiguous sequence of at least 30 amino acids, at least 80% identity with a peptide sequence ~~capable of being~~ encoded by at least a functional part of a reference nucleotide sequence selected from the group consisting of sequences of SEQ ID NOs: 1 to 15 and their complementary sequences.

3. (~~Twice Three Times Amended~~) ~~Nucleic~~ The nucleic material of the retroviral genomic type according to claim 1, comprising a nucleic fragment inserted between two sequences corresponding respectively to the LTR region and to the gag gene for the retroviral genomic structure.

4. (~~Twice Amended~~) ~~Nucleic~~ A nucleic material of the subgenomic retroviral type, consisting of a nucleotide sequence identical to SEQ ID NO: 11, with at least one deletion.

5. (~~Twice Amended~~) ~~Nucleic~~ A nucleic material according to claim 1, comprising at least one functional nucleotide sequence encoding at least one retroviral protein.

6. (~~Twice Amended~~) ~~Nucleic~~ A nucleic material according to claim 1, comprising at least one regulatory nucleotide sequence.

7. (~~Twice Three Times Amended~~) A nucleotide fragment ~~of at least 100 bases,~~ comprising a nucleotide sequence selected from the group consisting of:

(a) ~~all the nucleotide sequences, partial and complete, of a nucleic material according to claim 1;~~

~~b) all the a nucleotide sequences, partial and complete, of at least 100~~
bases of a clone selected from the group consisting of:

cl.6A2 (SEQ ID NO: 1),

cl.6A1 (SEQ ID NO: 2),

cl.7A16 (SEQ ID NO: 3),

cl.Pi22 (SEQ ID NO: 4),
cl.24.4 (SEQ ID NO: 5),
cl.C4C5 (SEQ ID NO: 6),
cl.PH74 (SEQ ID NO: 7),
cl.PH7 (SEQ ID NO: 8),
cl.Pi5T (SEQ ID NO: 9),
cl.44.4 (SEQ ID NO: 10),
HERV-W (SEQ ID NO: 11),
cl.6A5 (SEQ ID NO: 12),
cl.7A20 (SEQ ID NO: 13),
cl.7A21 (SEQ ID NO: 14), and
LTR (SEQ ID NO: 15);

e(b) ~~the~~ sequences which are respectively complementary to the sequences according to (a) ~~and b~~); and

d(c) ~~the equivalent~~ sequences which ~~are have~~ respectively ~~equivalent at~~ least 50% homology to the sequences according to ~~a), b) and c)~~ (a) and (b).

8. (~~Twice~~ Three Times Amended) A nucleic probe for the detection of a nucleic material, wherein said nucleic probe ~~is capable of hybridizing specifically~~ hybridizes under highly stringent conditions with the reference nucleotide sequence of the nucleic material according to claim 1.

9. (Twice Amended) A probe according to claim 8, comprising a ~~marker~~ label.

10. (~~Twice~~ Three Times Amended) A nucleic primer for the amplification by polymerization of an RNA or of a DNA, comprising a nucleotide sequence ~~capable of hybridizing specifically that~~ hybridizes under highly stringent conditions with the reference nucleotide sequence of the nucleic material according to claim 1.

18. (Twice Amended) A method for the molecular labeling of at least one member selected from the group consisting of an autoimmune disease, a pathology associated with an autoimmune disease, a pathological pregnancy, and an unsuccessful pregnancy, said method comprising:

at least one of identifying and/or and quantifying any nucleotide fragment according to claim 7 in any biological body material.

25. (Amended) Nucleic ~~The nucleic~~ material according to claim 1, wherein said ~~equivalent~~ reference nucleotide sequences exhibits, for ~~any every~~ sequence of 100 contiguous monomers, at least 90% homology with said sequences of SEQ ID NOs: 1 to 15, respectively.

26. (Amended) Nucleic ~~The nucleic~~ material according to claim 2, wherein said polypeptide exhibits, for ~~any every~~ contiguous sequence of at least 30 amino acids, at least 90% identity with a peptide sequence capable of being encoded by at least a functional part of said reference nucleotide sequence.

27. (Amended) Nucleic ~~The nucleic~~ material of the retroviral genomic type according to claim 2, comprising a nucleic fragment inserted between two sequences corresponding respectively to the LTR region and to the gag gene for said retroviral genomic structure.

28. (Amended) Nucleic ~~The nucleic~~ material according to claim 27, wherein said nucleic fragment comprises the sequence of SEQ ID NO: 12.

29. (Amended) Nucleic ~~The nucleic~~ material according to claim 3, wherein said nucleic fragment comprises the sequence of SEQ ID NO: 12.

30. (Amended) Nucleic ~~The nucleic~~ material according to claim 4, wherein said nucleotide sequence comprises a sequence selected from the group consisting of the sequences of SEQ ID NOs: 7, 8 and 9.

31. (Amended) Nucleic ~~The nucleic~~ material according to claim 4, comprising at least one functional nucleotide sequence encoding at least one retroviral protein.

32. (Amended) Nucleic ~~The nucleic~~ material according to claim 4, comprising at least one regulatory nucleotide sequence.

34. (Amended) A nucleotide fragment according to claim 7, wherein said equivalent sequences exhibit, ~~for any sequence of 100 contiguous monomers,~~ at least 70% homology with the sequences according to a), ~~b) and c)~~ (a) and (b).

35. (Amended) A nucleotide fragment according to claim 7, wherein said equivalent sequences exhibit, ~~for any sequence of 100 contiguous monomers,~~ at least 90% homology with the sequences according to a), ~~b) and c)~~ (a) and (b).